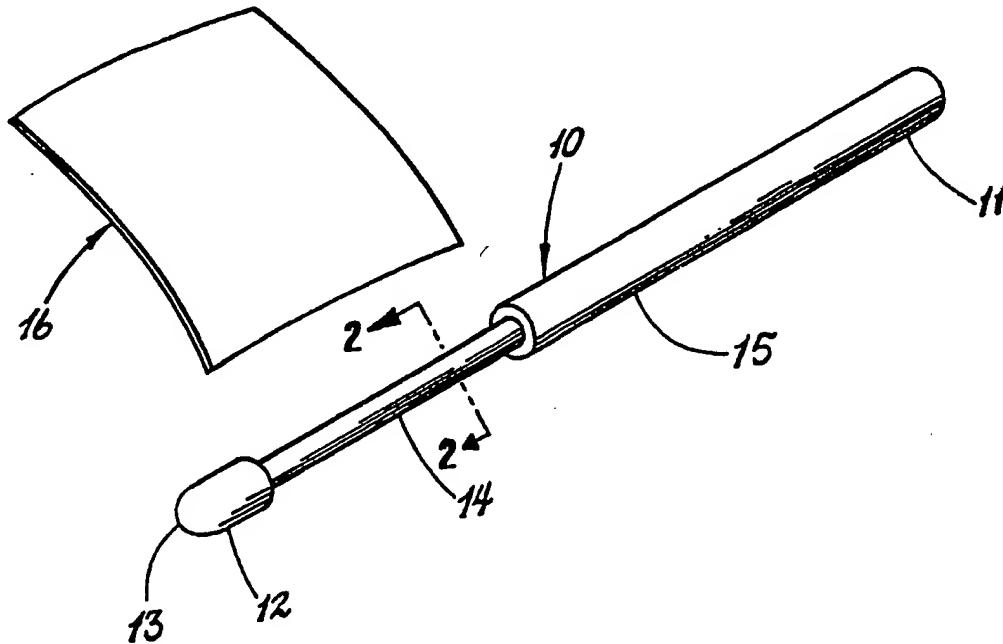




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 17/00		A1	(11) International Publication Number: WO 92/06638 (43) International Publication Date: 30 April 1992 (30.04.92)
(21) International Application Number: PCT/US91/07425 (22) International Filing Date: 7 October 1991 (07.10.91)		(74) Agents: SAMUELS, Gary, A. et al.; W.L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).	
(30) Priority data: 598,465 10 October 1990 (10.10.90) US		(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).	
(71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).		Published <i>With international search report.</i>	
(72) Inventors: O'HARA, Thomas, M. ; 53 Pine Dell Drive, Flagstaff, AZ 86001 (US). JANSEN, David, W. ; 1709 N. San Francisco, Flagstaff, AZ 86001 (US).			

(54) Title: A LAPAROSCOPY SURGICAL INSTRUMENT



(57) Abstract

A surgical instrument (10) for use in laparoscopy surgeries, useful for implanting prosthetic sheet repair materials (16) when surgical repair of body membranes or wall structures is required. The use of the inventive surgical instrument (10) minimizes the length of incision required to implant a piece of prosthetic sheet repair material (16).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU+	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE*	Germany	MC	Monaco	US	United States of America

+ Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

TITLE OF THE INVENTION**A Laparoscopy Surgical Instrument****FIELD OF THE INVENTION**

This invention relates to the field of surgical instruments, and
5 in particular to a surgical instrument for use in laparoscopy
surgeries to implant prosthetic sheet repair materials when surgical
repair of body membranes is required.

BACKGROUND OF THE INVENTION

The repair of weak or damaged body membranes or wall structures,
10 for example hernia repairs, peritoneal and pericardial repairs, is a
well known surgical art. Such repairs are typically made through
incisions large enough to allow the surgeon access to the defective
membrane with his hands. Repair of the defective membrane or wall
structure often requires the use of additional material in the form of
15 prosthetic sheet repair materials to reinforce the defective tissue.
These materials are typically in the form of porous flat sheets or
sheets of mesh having visibly open spaces between the components of
the mesh. They are usually made of biocompatible polymers such as
polytetrafluoroethylene, polyethylene terephthalate or polypropylene;
20 alternatively they may be made of bioabsorbable materials such as
oxidized regenerated cellulose, polyglycolic acid, polylactic acid or
copolymers thereof. The repair is typically accomplished by suturing
the perimeter of the prosthetic sheet repair material to the body
membrane in such a manner that the defective portion of the body
25 membrane is covered by the prosthetic sheet repair material. The
mechanical stresses normally carried by the body membrane or wall
structure are largely transferred to the sheet of prosthetic repair
material and to the sutures or other surgical fasteners used to retain
that material in place. It is apparent that an incision adequate to
30 allow access by a surgeon's hands so that the prosthetic sheet repair
material may be properly sutured into place will have to be of
substantial length. The resulting surgical trauma and time required
for healing are also substantial.

SUBSTITUTE SHEET

-2-

SUMMARY OF THE INVENTION

This invention relates to a surgical instrument for use in implanting prosthetic sheet repair materials for the repair of defective body membranes or wall structures via incisions of reduced length. The inventive surgical instrument comprises in its simplest embodiment a length of rod having an outside diameter and first and second ends, wherein said rod has adjacent to the first end a short length of reduced outside diameter in comparison to the rod outside diameter. A sheet of prosthetic repair material may be wrapped around the portion of the rod having the short length of reduced diameter, then inserted through a trocar sleeve previously placed into the appropriate body cavity via a small incision, to a position in close proximity to the defective body membrane or wall structure requiring repair. By rotating the rod in the direction appropriate to cause the rolled-up prosthetic sheet material to unroll, the prosthetic sheet material is presented to the site requiring repair. Forceps may be used to aid in unrolling the prosthetic sheet repair material from the rod. The tip of the inventive surgical instrument may be used to maneuver the sheet of prosthetic repair material as necessary into place over the defect site. The prosthetic sheet repair material may be fastened into place over the defect site by the use of various types of surgical fasteners, for example, as described in U.S. Patent 4,873,976. Other embodiments of the present invention include the use of a flexible shaft or handle portion and an embodiment wherein the shaft or handle portion is separately rotatable from the reduced diameter portion. The shaft or handle portion may also be made to be removable from the reduced diameter portion; the reduced diameter portion may incorporate a slot through its diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

30 Figure 1 shows a perspective view of the surgical instrument of the present invention and a sheet of prosthetic repair material for use with the surgical instrument.
Figure 2 shows a cross section of the reduced diameter portion of the surgical instrument of the present invention

-3-

Figure 3 shows a perspective view of the surgical instrument of the present invention during surgical use wherein a sheet of prosthetic repair material is shown wrapped around the reduced diameter portion of the instrument.

5 Figure 4 shows a cross section of the reduced diameter portion of the surgical instrument of the present invention during surgical use wherein a sheet of prosthetic repair material is shown wrapped around the reduced diameter portion of the instrument.

10 Figure 5 shows a cross section of the reduced diameter portion of an alternative embodiment of the surgical instrument wherein a slot exists through the length of the reduced diameter portion.

15 Figure 6 shows the cross section of the surgical instrument of Figure 5 in use, wherein a sheet of prosthetic repair material is shown wrapped around the reduced diameter portion of the instrument with one edge of the prosthetic sheet inserted through the slot in the instrument.

Figure 7 shows a perspective view of one embodiment of the surgical instrument wherein the shaft portion of the instrument is a flexible shaft.

20 Figure 8 shows a perspective view of one embodiment of the surgical instrument wherein the shaft portion of the instrument comprises a removable handle.

25 Figure 9 shows a longitudinal cross section of one embodiment of the surgical instrument wherein the shaft portion and the reduced diameter portion incorporate mating rotating means so that the two portions are rotatable relative to each other.

DETAILED DESCRIPTION OF THE INVENTION

As shown by the perspective view of Figure 1, the surgical instrument 10 of the present invention comprises a length of rod 30 having a second end 11 and a first end 12 having a portion 14 of said length with a reduced diameter adjacent to the first end 12. The tip 13 of the instrument 10 is radiused to allow smooth entry via an incision into the body cavity. For convenience, the remaining length 15 of the rod-like instrument 10 will be referred to as the shaft. A 35 piece of prosthetic sheet repair material 16 is shown adjacent to the

SUBSTITUTE SHEET

-4-

reduced diameter portion 14 of the instrument 10 in position to be rolled up around the reduced diameter portion 14.

Figure 2 shows the round cross section, taken at A-A', of the cylindrical form of the reduced diameter portion 14.

5 Figure 3 describes the appearance of the instrument 10 during use at which time the piece of prosthetic sheet repair material 16 is rolled up around the reduced diameter portion 14. The same appearance is shown in the cross section of Figure 4 taken at B-B'.

An alternative embodiment is described in the cross section of
10 Figure 5 wherein the reduced diameter portion has a slot 17 cut through the reduced diameter portion 14 for the entire length of that portion. The slot 17 is typically centered over a diameter of the reduced diameter portion 14 and is of width slightly greater than the thickness of the prosthetic repair material. As shown by Figure 6, an
15 edge 18 of the prosthetic sheet repair material 16 may be inserted into the slot 17 prior to rolling the repair material around the reduced diameter portion 14 of the instrument. A piece of prosthetic sheet repair material 16 is shown in the cross section of Figure 6, wherein the sheet is shown rolled-up around the reduced diameter
20 portion 14 of the surgical instrument of this embodiment with one edge 18 of the prosthetic sheet material 16 inserted through the slot 17 in the instrument.

Figure 7 shows another alternative embodiment wherein the shaft portion 15 adjacent to the second end of the instrument comprises a
25 flexible shaft. By flexible is meant that the shaft is bendable or incorporates a swivel to allow the instrument to be used with the handle or shaft portion set at an angle to the reduced diameter portion. This may be advantageous for certain applications.

Figure 8 shows still another alternative embodiment wherein the shaft portion adjacent to the second end of the instrument is
30 removable from the remainder of the instrument and so comprises a removable handle 19. This may be accomplished by the use of a threaded connection or any other means for removing and reattaching. This may be useful for applications wherein a single handle may be
35 provided for use with various types of instruments including the surgical instrument of the present invention.

Figure 9 shows a longitudinal cross section of still another alternative embodiment wherein the shaft portion or handle 19 adjacent

-5-

to the second end of the instrument and the reduced diameter portion 14 of the instrument incorporate mating rotating means such as the ball and socket joint 20 shown. The shaft portion or handle 19 may or may not be made to be removable from the reduced diameter portion 14

5 at the mating rotating means 20. This embodiment allows the reduced diameter portion of the instrument to be separately rotated from the shaft portion of the instrument. This may be useful for applications wherein it is desired to unroll the prosthetic sheet repair material from the reduced diameter portion 14 of the instrument while the shaft

10 portion or handle 19 is held stationary.

The surgical instrument of the present invention may be made of any suitable material that possesses adequate rigidity, is biocompatible, easily cleaned and is sterilizable. Stainless steels suitable for surgical instruments are preferred.

15 The surgical instrument is intended for use primarily with GORE-TEX® Surgical Membrane (W. L. Gore & Associates, Inc., Flagstaff, Arizona) or the thicker GORE-TEX® Soft Tissue Patch material (W. L. Gore & Associates, Inc., Flagstaff, Arizona) which is intended primarily for reconstruction of hernias. Both of these products are

20 comprised of porous polytetrafluoroethylene. This material has almost no memory, so that when it is rolled-up around the reduced diameter of the inventive surgical instrument it has almost no tendency toward unrolling. Conversely, when unrolled from the instrument at a surgical site requiring repair, it displays almost no tendency to want

25 to resume its rolled-up form.

The inventive surgical instrument is typically used as follows. A laparoscopy incision is made convenient to the defect site. A suitable trocar sleeve is then inserted into the incision. A piece of prosthetic repair material of a suitable type is cut to the necessary

30 shape, rolled-up around the reduced diameter portion of the instrument, and delivered to the defect site through the bore of the trocar sleeve. The surgical instrument is then rotated in such a way as to unroll the prosthetic sheet repair material and present it in flat form to the defect site. Forceps, introduced via another trocar

35 sleeve, may be used to unroll or aid in unrolling the prosthetic repair material from the surgical instrument. The tip of the surgical instrument and the forceps may subsequently be used to position the prosthetic repair material as required over the defect site. The

-6-

repair material may then be attached to the defect site by any suitable surgical fastening means. The procedure may be viewed as necessary with a suitable laparoscope.

EXAMPLE

- 5 The abdomen of a female, foxhound-cross dog was implanted with a GORE-TEX Surgical Membrane, using only laparoscopy. A standard 10mm trocar sleeve was emplaced near the abdominal midline via a 2 cm long incision. A standard 5mm trocar sleeve was emplaced at the right lateral abdominal sidewall via a second incision. A 10mm operating
- 10 laparoscope was introduced through the 10mm sleeve. A 3 x 3cm GORE-TEX Surgical Membrane was wrapped around a surgical instrument of the present invention. The instrument, made of stainless steel, was of 5 cm length, 5 mm outside diameter, with a reduced length segment of 3 mm diameter and 8.5 mm length beginning 10 mm from the end of the
- 15 instrument. The instrument was then introduced to the abdominal cavity through the operating channel of the laparoscope. An atraumatic forceps, passed through the 5mm sleeve, was used to grasp the GORE-TEX Surgical Membrane and unwrap it. The forceps was then used to place the Surgical Membrane along the left abdominal sidewall.
- 20 A specially designed "tack gun" loaded with a single stainless steel barbed tack similar to those described in U.S. Patent 4,873,976 was introduced through the 5mm sleeve. A tack was then placed into the abdominal wall, through the GORE-TEX Surgical Membrane, securely pinning the surgical membrane to the abdominal wall. Three tacks were
- 25 thus used to implant the GORE-TEX Surgical Membrane. The GORE-TEX Surgical Membrane became slightly wrinkled as tension was not applied to the repair material with the forceps during placement of the tacks. It appeared that wrinkling would be avoided by the use of tension via forceps.
- 30 Twenty-four days post operatively, the animal was euthanized. The implant site was removed and preserved in formalin. The prosthetic repair material remained wrinkled, but the tacks were in place and had held the GORE-TEX Surgical Membrane. No adverse tissue reaction could be seen grossly at the GORE-TEX Surgical Membrane site.

We Claim:

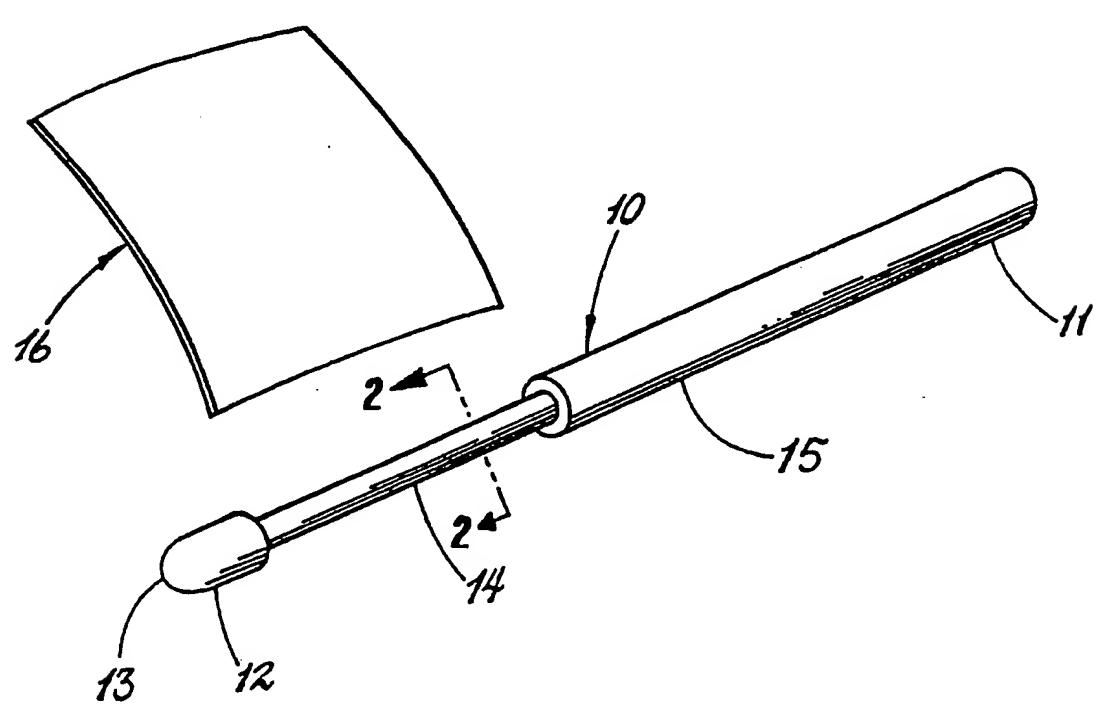
1. A surgical laparoscopy instrument comprising a rod having a length, an outside diameter and first and second ends, further having a portion of said length adjacent to the first end wherein
5 said length portion has a reduced outside diameter in comparison to the rod outside diameter.
2. A surgical laparoscopy instrument according to claim 1 wherein the instrument is comprised of stainless steel.
3. A surgical laparoscopy instrument according to claim 1 wherein
10 said length portion has a slot through the reduced diameter.
4. A surgical laparoscopy instrument according to claim 3 wherein the instrument is comprised of stainless steel.
5. A surgical laparoscopy instrument according to claim 1 wherein at least a part of the length of said rod adjacent to the second end
15 is comprised of a flexible shaft.
6. A surgical laparoscopy instrument according to claim 1 wherein at least a part of the length of said rod adjacent to the second end is removable from the length portion having the reduced outside diameter and comprises a removable handle.
- 20 7. A surgical laparoscopy instrument according to claim 1 wherein a part of the length of said rod adjacent to the second end and the length portion having the reduced diameter have a mating rotating means whereby the length portion having the reduced outside diameter may be rotated relative to the part of the length of the
25 rod adjacent to the second end.
8. A surgical laparoscopy instrument according to claim 6 wherein a part of the length of said rod adjacent to the second end and the length portion having the reduced diameter have a mating rotating means whereby the length portion having the reduced outside
30 diameter may be rotated relative to the part of the length of the rod adjacent to the second end.
9. A process of implanting a prosthetic sheet repair material comprising:
 - a) making a surgical incision in a body;
 - 35 b) inserting a hollow sleeve into the body through the incision;

-8-

- c) rolling a sheet of prosthetic sheet repair material around a reduced diameter portion of a surgical laparoscopy instrument comprising a rod having adjacent to one end the reduced diameter portion;
- 5 d) inserting said laparoscopy instrument and prosthetic sheet repair material into the incision through the hollow sleeve;
- e) unrolling the sheet of prosthetic repair material from the surgical laparoscopy instrument;
- f) fastening the sheet of prosthetic repair material within the
- 10 body by surgical fastening means;
- g) removing the laparoscopy instrument and hollow sleeve from the body; and
- h) closing the incision.

1/6

FIG. 1



2/6

FIG. 2

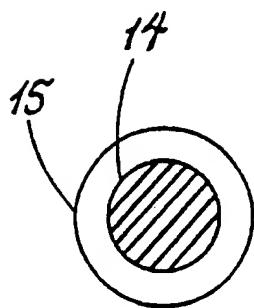
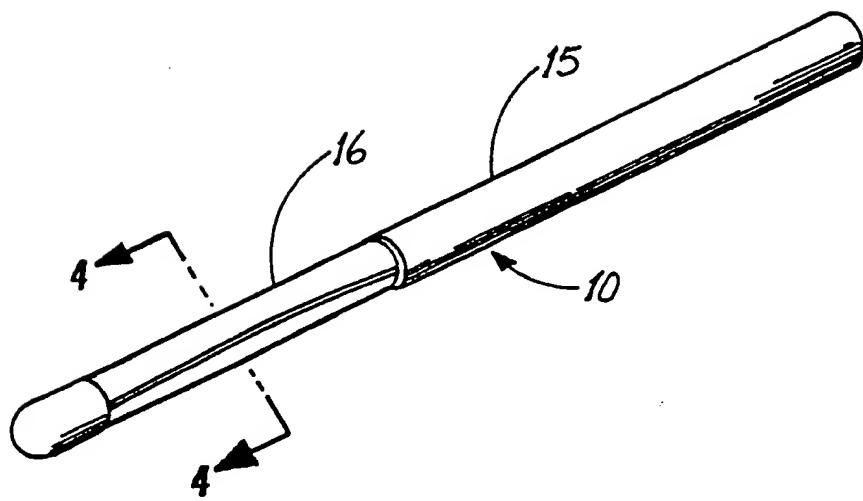


FIG. 3



3/6

FIG. 4

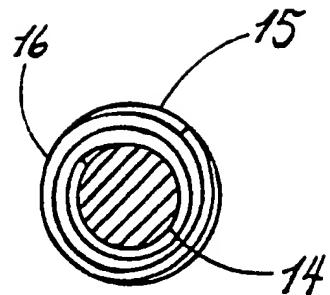


FIG. 5

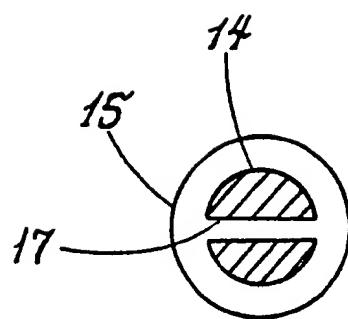
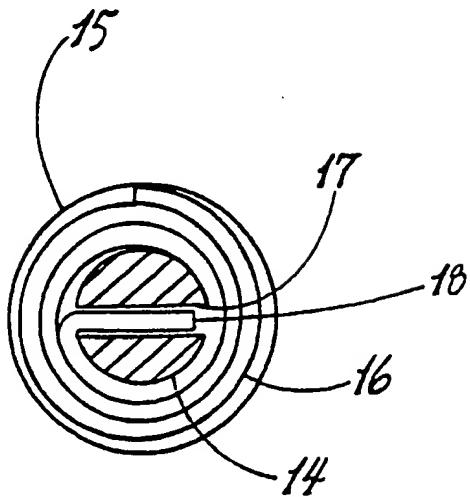
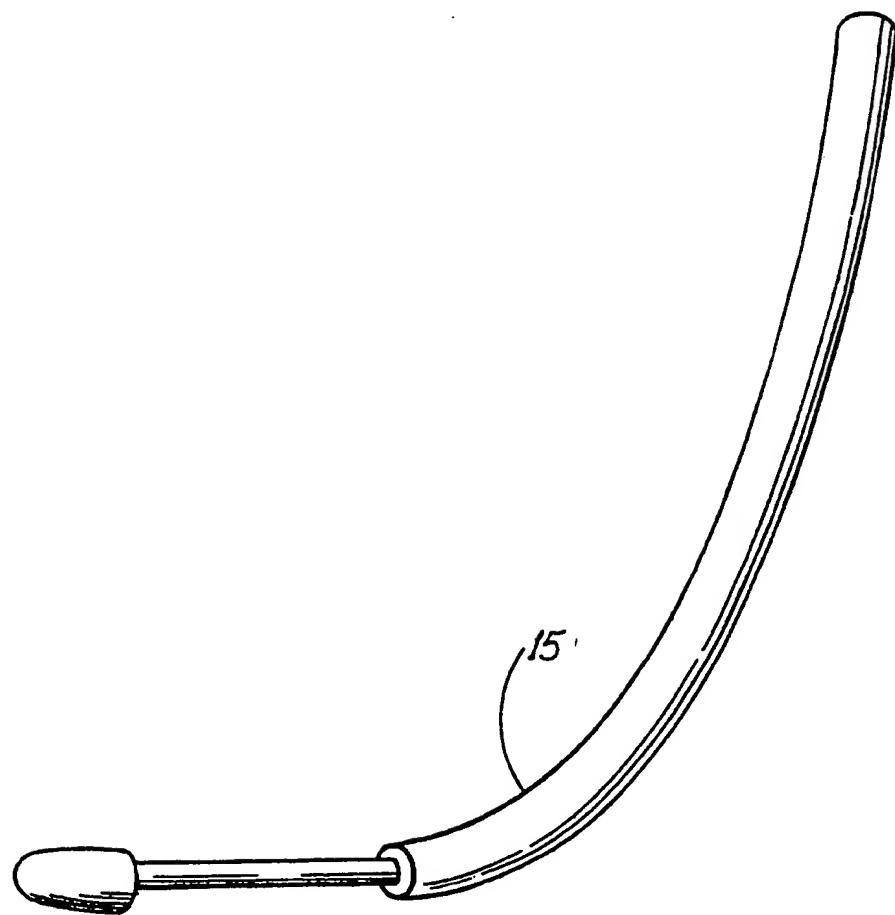


FIG. 6



4/6

FIG. 7



5/6

FIG. 8

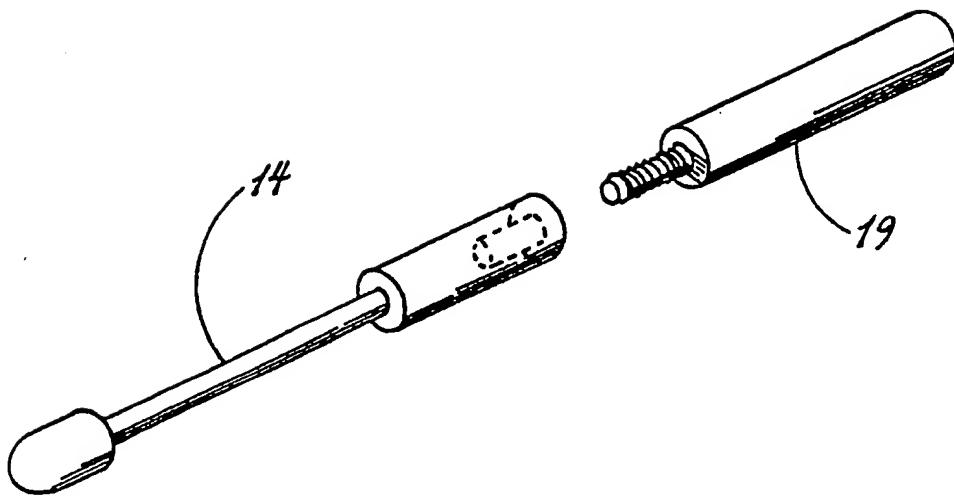
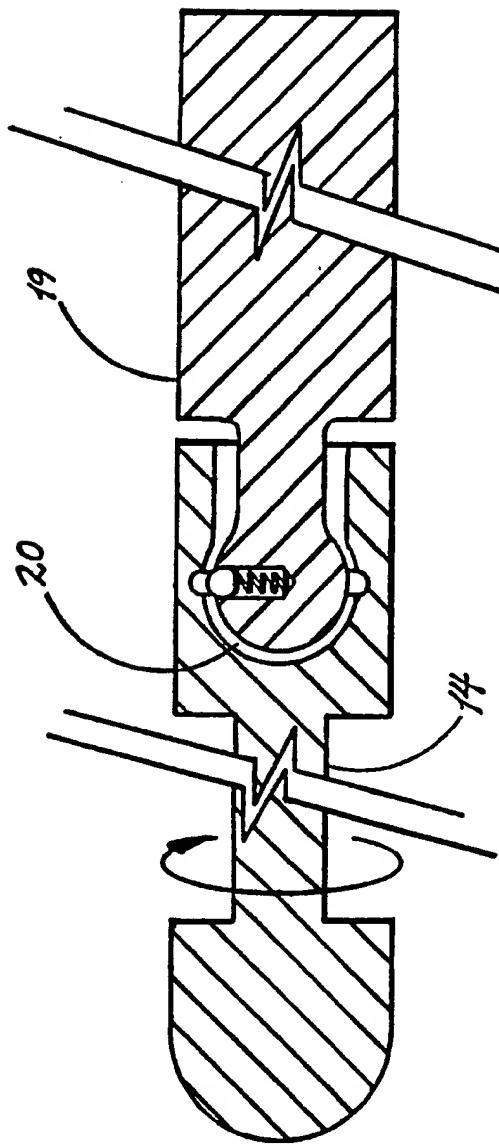


FIG. 9



INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/07425

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.C1.5 A 61 B 17/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.C1.5	A 61 B	A 61 F
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A,4291694 (CHAI) 29 September 1981, see abstract; column 3, lines 41-61; figure 1 ---	1,5
A,P	US,A,5007895 (BURNETT) 16 April 1991, see abstract; figures ---	1
A	DE,U,8900439 (MULLER) 23 March 1989, see claim 1; figures ---	7,8
A	DE,A,3217006 (KAUTZ) 10 November 1983 -----	
<p>* Special categories of cited documents :¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"Z" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
20-12-1991	12.02.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE		

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. OBSERVATION WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim numbers 9 because they relate to subject matter not required to be searched by this Authority, namely:
see PCT-Rule 39.1(iv)
2. Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically.
3. Claim numbers the second and third sentences of PCT Rule 6.4(a). because they are dependent claims and are not drafted in accordance with

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this International application as follows:

1. As all required additional search fees were timely paid by the applicant, this International search report covers all searchable claims of the International application
2. As only some of the required additional search fees were timely paid by the applicant, this International search report covers only those claims of the International application for which fees were paid, specifically claims:
3. No required additional search fees were timely paid by the applicant. Consequently, this International search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

The additional search fees were accompanied by applicant's protest.
 No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.

US 9107425
SA 52739

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 21/01/92. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4291694	29-09-81	None	
US-A- 5007895	16-04-91	None	
DE-U- 8900439	23-03-89	None	
DE-A- 3217006	10-11-83	None	